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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,766	06/20/2002	Martinas Kuslys	112843-043	2286

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EXAMINER

HINES, JANA A

ART UNIT	PAPER NUMBER
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1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/19/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/088,766

Applicant(s)

KUSLYS ET AL.

Examiner

Ja-Na Hines

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-10 and 13-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-10 and 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 16, 2007 has been entered.

Amendment Entry

2. The amendment filed January 16, 2007 has been entered. Claims 1, 10, 13, and 20 have been amended. Claims 2, 5, and 11-12 have been cancelled. Claims 1, 3, 4, 6-10 and 13-20 are under consideration in this office action.

Response to Arguments

3. Applicant's arguments, see also the affidavit of Dr. Kuslys, filed January 16, 2007, with respect to the rejection of claims 1, 3, 4, 6-10 and 13-20 under 35 U.S.C. 103(a) as being unpatentable over JP-002158762 in view of Erdmann et al., have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

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Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground of rejection. However, upon further consideration, a new ground of rejection is made in view of JP-002158762 in view of Georgi et al.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 3, 4, 6-10 and 13-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claims 1, 10, 13 and 20 are unclear. The claim language in each claim is drawn to "ingredient selected from the group consisting of milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan and mixtures thereof" is unclear. It is unclear how to interpret the "amino acids as tryptophan, free tryptophan and mixtures thereof". It appears the claims are drawn to a Markush group requiring the selection of amino acids; but the claims state selection of an ingredient from a group of milk proteins. Tryptophan and free tryptophan are amino acids, not milk proteins. Therefore the relationship between the ingredient, the milk protein and the recited amino acids is unclear.

b) Claim 14 is drawn to the formula of claim 13 comprising from 9.0 to 10% of protein, however it is unclear which protein of claim 13 is being referred to, i.e., the

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whey protein or the casein protein. Therefore clarification is required to overcome the rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1, 4, 6-7, 10, 13, 16-17, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yonekubo et al., (JP-002158742) in view of Georgi et al., WO 95/17102. WO 95/17102 provides priority to US Patent 5,916, 621; however US Patent 5,916,621 will reference the English language version of WO 95/17102.

Claims are drawn to a composition for an infant formula comprising: whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and an ingredient selected from the group consisting of milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan and mixtures thereof. Claim 13 is drawn to an infant formula comprising the same components.

Claim 10 is drawn to method of producing an infant formula, the method comprising the-step-of blending whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed, and casein protein together with free arginine; free histidine; and an ingredient selected from

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the group consisting of milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan and mixtures thereof and homogenizing the blended mixture. And claim 20 is drawn to a method of providing nutrition to an infant, the method comprising administering to the infant a composition comprising whey protein, wherein the whey protein is hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and an ingredient selected from the group consisting of milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan and mixtures thereof.

Yonekubo et al., teach highly digestible nutritive compositions for infant use (page 2). The nutritive composition comprises natural milk proteins, amino acids as the protein source and nutrients such as lipids (fats) and carbohydrates (page 2, lines 8-11). Casein, a tryptophan rich milk protein is at 24-32% by weight which has at level of 5% or more of tryptophan (page 2, lines 32-33). The whey protein is at 30-40% by weight while the casein protein is at 24-32% by weight (page 2). Thus, the amount of each is within the instantly claimed ranges. The whey powder obtained from the milk serum portion that is left after casein has been removed (page 3, lines 20-21). Therefore casein is removed from the whey to produce sweet whey. The whey powder is further treated and lactose is eliminated from it, thereby resulting in a product useable in a nutritive infant composition (page 3, lines 21-22). The composition uses highly desirable natural proteins and adds essential amino acids to fortify the proteins, thereby reducing the overall protein content (page 3, lines 2-7). The amino acids used in the compositions are free amino acids (page 3, lines 24-25). The composition comprises

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histidine at 1.4 to 2.0% by weight and has tryptophan is at 0.5-0.7% by weight (page 3).

It is noted that Yonekubo et al., teach different concentrations for the arginine and tryptophan, however limitations such as different concentrations are viewed as limitations not imparting patentability. There is no evidence that these limitations provide unexpected results. The composition reduces the levels of protein ingested, provides natural proteins that are beneficial in terms of digestive absorption, succeeds in reducing total protein levels while providing supplementary essential amino acids (page 3, lines 2-5).

Yonekubo et al., teach a method of making the infant formulas, see Working Example 1. The nutritive composition can be easily digested and utilized by babies and infants (page 2, lines 5-7). Yonekubo teach in order to provide optimal emulsification and homogenization, the addition of surface active agents is necessary (page 3, lines 38-40). The components are homogeneously mixed and formulated into a powder thereby yielding an infant use nutritive composition (page 4, lines 18-22). Therefore the composition has been blended and homogenized. The composition is administered by dissolution in water and then administering it to an infant (page 5, lines 3-5). However Yonekubo et al., do not teach the use of hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed.

Georgi et al, teach that it is important to use whey powder/proteins that do not contain glycomacropeptide (GMP) because GMP causes the very high threonine content (col. 1-2, lines 65-2). It is noted that high threonine levels in infants causes hyperthreoninemia. Georgi et al., teach the production of milk baby foods, which have

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whey protein as the dominant product in such foods (col.1, lines 18-21). Milk baby foods have the disadvantage of having a high threonine content that causes high levels of threonine in the plasma of infants (col. 1, lines 20-25). Georgi et al., found that threonine content in whey powders are higher due to the addition of whey proteins (col.1, lines 37-41). Therefore Georgi et al., teach the need for whey protein dominant milk baby food or formula with a reduced threonine content (col.1, lines 42-45). Whey powder or whey proteins used in the production of milk baby foods are obtained exclusively from sweet whey which is produced by the precipitation and removal of caseins (col. 1, lines 51-55). GMP must be completely removed by suitable processes; and removal processes are commercially well known (col.2, lines 5-14). The sweet whey after the removal GMP is further hydrolysed with enzymes according to known processes (col.2, lines 50-52). Therefore Georgi et al, teach the use of hydrolysed sweet whey protein from which caseino-glyco-macropeptide has been removed.

Therefore it would have been prima facie obvious at the time of applicants' invention to modify the sweet whey composition for an infant formula, along with the method of production and method of providing an infant formula as taught by Yonekubo et al., wherein the modification incorporates the use of hydrolysed sweet whey protein from which casein-glyco-macropeptide has been removed as taught by Georgi et al. One of ordinary skill in the art would be motivated to modify the compositions and methods as taught by Yonekubo et al., because Georgi et al., teach that providing formula without high threonine levels is advantageous to infants and that by removing the GMP from whey, one of ordinary skill in the art can provide formula with significantly

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reduced the threonine levels which is beneficial to infants. No more than routine would have been required to modify the composition and method of Yonekubo et al., by incorporating the hydrolysed sweet whey when Yonekubo et al., and Georgi et al., teach that the removal of casein-glyco-macropeptide and the hydrolysis of sweet whey are performed by used well known processes and desirable in infant formulations.

Moreover, one of ordinary skill in the art would have a reasonable expectation of success since well known commercially available methods were used to formulate the infant formulas and method of production and administration which had been routinely observed in the prior art to provide baby formulas with reduced threonine content by adding GMP free whey proteins which are dominant in baby milk foods. Furthermore, the limitations drawn to the different concentrations for the arginine and tryptophan are viewed as merely optimizing the experimental parameters and not imparting patentability; thus no more than routine skill would have been required to change the concentration in the well known compositions and method of production as taught by Yonekubo et al., in view of Georgi et al.

Conclusion

6. No claims allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Jeffery Siew, can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
April 7, 2007



JEFFREY SIEW
SUPERVISORY PATENT EXAMINER